22-2153 and 23-1952

United States Court of Appeals for the Federal Circuit

SALIX PHARMACEUTICALS, LTD., SALIX PHARMACEUTICALS, INC., BAUSCH HEALTH IRELAND LTD., ALFASIGMA S.P.A.,

Plaintiffs-Appellants,

– v. –

NORWICH PHARMACEUTICALS INC.,

Defendant-Cross-Appellant.

On Appeal from the United States District Court for the District of Delaware in No. 1:20-cv-00430-RGA, Honorable Richard G. Andrews, Judge

REPLY BRIEF FOR DEFENDANT-CROSS-APPELLANT

CHAD A. LANDMON
MATTHEW J. BECKER
MATTHEW S. MURPHY
THOMAS K. HEDEMANN
REBECCA L. CLEGG
AXINN, VELTROP & HARKRIDER LLP
90 State House Square
Hartford, Connecticut 06103
(860) 275-8100
clandmon@axinn.com
mbecker@axinn.com
mmurphy@axinn.com
thedemann@axinn.com
rclegg@axinn.com

Counsel for Defendant-Cross-Appellant

OCTOBER 23, 2023

CP COUNSEL PRESS (800) 4-APPEAL • (324965)

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 22-2153, 23-1952

Short Case Caption Salix Pharmaceuticals, Ltd. v. Norwich Pharmaceuticals, I

Filing Party/Entity Norwich Pharmaceuticals Inc.

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
4. Please do not duplicate entries within Section 5.
5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 10/23/2023 Signature: /s/ Chad A. Landmon

Name: Chad A. Landmon

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Norwich Pharmaceuticals, Inc.		Alvogen Pharma US, Inc.
		Alvogen Group, Inc.
		New Alvogen Group Holdings, Inc.
		Alvogen Lux Holdings S.a.r.l.
		Aztiq Pharma Partners S.a.r.l.

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☐ Additional pages attached

Aziz Burgy, Axinn, Veltrop, & Harkrider LLP	Stacie Ropka, Axinn, Veltrop, & Harkrider LLP	Ricky Camposanto, Axinn, Veltrop, & Harkrider LLP
David Fry, Shaw Keller LLP (formerly)	Karen Keller, Shaw Keller LLP	Nate Hoeschen, Shaw Keller LLP

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☑ Yes (file separate notice; see below) ☐ No ☐ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Other Authorities

INTRODUCTION

Salix's responsive brief is short on arguments relevant to the correct interpretation of Section 271(e)(4)(A) – the central question on appeal – and long on unfounded claims of prejudice that have no bearing on statutory interpretation. Moreover, the prejudice here is to Norwich, who is being kept from marketing its rifaximin product for IBS-D without any basis in statute, regulation, or patent law, as well as to patients and the healthcare system that continue to pay monopoly prices for Salix's branded product.

Regarding the interpretation of Section 271(e)(4)(A), which the parties agree is subject to *de novo* review, Salix does not deny that its reading of the key term "the drug . . . involved in the infringement" as merely identifying the subject of the 271(e) order renders it redundant because the subject of the order is already identified earlier in the Section. Salix's interpretation is therefore contrary to the "cardinal principle" that no term should be construed so as to make it "superfluous, void, or insignificant." *Duncan v. Walker*, 533 U.S. 167, 174 (2001). By contrast, Norwich's interpretation of the term as a qualifier on the scope of the 271(e) order imbues the term with meaning and ensures that 271(e) orders are tailored to the actual act of infringement under Section 271(e)(2)(A).

Furthermore, Norwich's interpretation aligns Section 271(e)(4)(A) with the broader scope and goals of the Hatch-Waxman Act as well as with FDA's

implementing regulation. Salix's interpretation, by contrast, eviscerates the section viii mechanism Congress provided to ensure that approval of an ANDA would not be delayed by patents on an indication for which the ANDA does not seek approval. Salix's interpretation also renders meaningless FDA's regulation permitting ANDA applicants to utilize the section viii mechanism *after* a finding of infringement. Still further, Norwich's interpretation accords with the general principle of patent law that an injunction should be tailored to the infringement, whereas Salix's interpretation requires 271(e) orders to extend beyond the infringement found under Section 271(e)(2)(A).

Indeed, Salix cannot articulate any principled reason as to why Congress would have intended for a district court to issue a 271(e) order that delays FDA approval of an ANDA for any reason other than the basis for which the ANDA infringes a patent. And there is none. Salix points to the custom of referencing the ANDA number in 271(e) orders but ignores that the greater specificity required by the statute has no practical import outside the rare case where, such as here, there are at least two distinct approved indications covered by different method-of-use patents and no other patent barrier.

Salix's claims of unfairness or prejudice also fall flat. Salix has enjoyed the full benefit of the 30-month stay provided by the Hatch-Waxman Act while its patents were litigated. And Salix's claim that it might have chosen a different

litigation or trial strategy had Norwich amended its ANDA earlier is undermined by the fact that it elected to try only eight of the twenty patent claims it was permitted to pursue at trial. Moreover, Salix's strategy with respect to the HE Patents was successful – it defended their validity and secured a continued monopoly on marketing rifaximin for the HE Indication. The only unfairness here is to Norwich, who is unable to obtain FDA approval for its Amended ANDA despite having undertaken the burden and expense of proving that Salix's Polymorph and IBS-D patents are invalid before following the roadmap provided by Congress and FDA to amend its ANDA and remove the infringing HE Indication.

Finally, Salix fails to rebut that the District Court's denial of Norwich's Rule 60(b)(5) motion was based on legal error and an abuse of discretion. The court was simply incorrect when it held that the "satisfied, released, or discharged" prong of the rule only applies to money damages, and that the "equitable" prong only applies when the change in circumstances was unanticipated or unforeseen. It also erred when it dismissed Norwich's motion under Rule 60(b)(6) on the incorrect premise that Norwich did not assert that part of the rule. None of these errors are seriously disputed by Salix. When the facts are properly applied to the Rule and applicable case law, Norwich's motion should have been granted and the

Final Judgment and 271(e) order amended to accurately reflect the underlying act of infringement.

ARGUMENT

I. THE DISTRICT COURT LEGALLY ERRED IN FAILING TO REFERENCE THE HE INDICATION IN THE 271(e) ORDER.

A. Salix Admits that Its Interpretation Renders the Statutory Language Redundant.

Salix confirms that the interpretation of Section 271(e)(4)(A) it advocates and that the District Court adopted reads the term "the drug . . . involved in the infringement" merely as identifying the drug to which the 271(e) order should be directed. Response and Reply Brief of Appellants ("Salix Responsive Br.") at 40. Yet Salix does not dispute that the relevant drug is *already* identified in Section 271(e)(4)(A) by way of its reference to the "act of infringement" defined in Section 271(e)(2)(A). Plainly, the "act of infringement" cannot be determined without identification of that which infringes. Principal and Response Brief for Defendant-Cross-Appellant ("Norwich Br.") at 15. Salix's interpretation thus renders the term "the drug . . . involved in the infringement" in Section 271(e)(4)(A) wholly redundant and mere surplusage. It therefore fails the "cardinal principle of statutory construction" that "a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be

superfluous, void, or insignificant." *Duncan*, 533 U.S. at 174 (quotation and citation omitted).[1] Salix's interpretation should be rejected for this reason alone.

Furthermore, Salix's contention that the "act of infringement" in Section 271(e)(2)(A) is "the filing of the ANDA application" leaves out the relevant portion of the definition. Salix Responsive Br. at 40. In fact, the statutory "act of infringement" is the submission of an ANDA to obtain regulatory approval "*for a drug claimed in a patent or the use of which is claimed in a patent* …." 35 U.S.C. § 271(e)(2)(A) (emphasis added).[2] Therefore, "an ANDA seeking to market a drug not covered by a composition patent for unpatented methods of treatment cannot infringe under § 271(e)(2)." *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1379 (Fed. Cir. 2012).

[1] Salix asserts but never explains how a 271(e) order referencing only the ANDA number is "[c]onsistent with the statute's plain text," i.e., "the drug . . . involved in the infringement." Salix Br. at 39. An ANDA contains much more information than just a characterization of the drug substance. Thus, "ANDA No. 214369" is not co-extensive with "rifaximin," for example.

[2] Salix also makes a confused argument about "the infringement" referring to the "past" act of submitting the ANDA. Salix Br. at 41. Of course, the Hatch-Waxman Act makes the ANDA submission (which may be subject to amendments) an "artificial" act of infringement for purposes of vesting jurisdiction with the district court. But "once jurisdiction is established, the ultimate infringement inquiry provoked by such filing is focused on a comparison of the asserted patent claims against the product that is likely to be sold following ANDA approval and determined by traditional patent law principles." *Ferring B.V. v. Watson Lab'ys, Inc.-Fla.*, 764 F.3d 1401, 1408 (Fed. Cir. 2014) (citing cases).

Finally, Salix's argument that "the infringement" found by the District Court was the submission of the original ANDA with the HE Indication only supports Norwich. Salix Responsive Br. at 41. The salient point is that the District Court has *not* found that Norwich's Amended ANDA *without* the HE Indication infringes under Section 271(e)(2)(A). Indeed, it was never asked to consider that issue. The District Court only determined that rifaximin – "the drug" – is "involved in the infringement" when the ANDA seeks approval for and contains labeling for the HE Indication. There is consequently no predicate for a 271(e) order delaying approval of the Amended ANDA, which does not contain labeling for the HE Indication or a Paragraph IV certification to the HE Patents. The fact is that the statutory interpretation urged by Salix has resulted in a 271(e) order that FDA deems to be blocking an ANDA that does *not* seek approval for any indication covered by a valid Orange-Book patent. That absurd result demonstrates that Salix's interpretation cannot be correct. *See, e.g., Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982) ("[I]nterpretations of a statute which would produce absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available.").

B. Salix Cannot Reconcile Its Interpretation With the Goals and Provisions of the Hatch-Waxman Act.

Courts interpreting statutory language consider "the whole statute . . . and the objects and policy of the law . . . and give it such a construction as will carry

into execution the will of the Legislature." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1355 (Fed. Cir. 2003). Salix's interpretation, however, runs contrary to the goals and provisions of the Hatch-Waxman Act.

There can be no dispute that bringing "'generic … drugs to market as quickly as possible'" is a central purpose of the Hatch-Waxman Act. *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) (quoting Sen. Kennedy Remarks, 149 Cong. Rec. S15885 (Nov. 25, 2003)). As Norwich explained (Norwich Br. at 19-20), Congress achieved this goal in part by including the section viii mechanism that permits ANDA filers to obtain approval for indications that are *not* covered by any valid patents listed in the Orange Book. *See, e.g., Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 415 (2012) ("The Hatch-Waxman Amendments authorize the FDA to approve the marketing of a generic drug for particular unpatented uses; and section viii provides the mechanism for a generic company to identify those uses, so that a product with a label matching them can quickly come to market."). And unlike a Paragraph IV certification, a section viii statement does not place any patent-related constraints on FDA approval of the ANDA. *See* 21 U.S.C. § 355(j)(5)(A)-(B). Yet the interpretation of Section 271(e)(4)(A) urged by Salix and adopted by the District Court has resulted in a 271(e) order that FDA deems to be blocking it from granting approval over patents for which the Amended ANDA

provides section viii statements. Far from executing "the will of the Legislature," therefore, Salix's interpretation eviscerates Congress' section viii mechanism here and delays generic entry.

Salix objects that the Hatch-Waxman Act seeks "to balance generic and brand interests." Salix Responsive Br. at 37. But Salix has never been able to explain how there could be a protectable "brand interest" in 271(e) orders that have a broader injunctive scope than the underlying act of infringement. And Salix has already received the benefit of the actual protections the Hatch-Waxman Act provides for brand companies, i.e., the full 30-month stay of FDA approval during which time its patents were litigated. Further delaying approval of Norwich's Amended ANDA based on patents covering an indication for which the ANDA does not seek approval distorts the balance that Salix points to.

C. Salix's Interpretation Is Contrary to FDA's Regulation.

As Norwich pointed out and Salix does not dispute, Congress did not place any temporal restriction on an ANDA applicant's use of the section viii mechanism. Norwich Br. at 20. FDA regulation thus permits the applicant to use this mechanism at any time, including by amending the ANDA "[a]fter [a] finding of infringement." 21 C.F.R. § 314.94(a)(12)(viii)(A). FDA's regulations also provide that an ANDA with a section viii statement may be approved "immediately." 21 C.F.R. § 314.107(b)(1)(ii).

FDA promulgated 21 C.F.R. § 314.94(a)(12)(viii)(A) in 2016 – more than 30 years after the enactment of Hatch-Waxman. The agency was consequently well aware of the fact that a 271(e) order always accompanies a finding of infringement under 271(e). It therefore must have interpreted Section 271(e)(4)(A) as permitting courts to fashion 271(e) orders that do not block approval of ANDAs that are amended to remove an infringing indication after a finding of infringement. In other words, FDA cannot have understood Section 271(e)(4)(A) as Salix urges here.

Salix argues that consistency with regulation is not "a canon of statutory construction." Salix Responsive Br. at 51. Perhaps, but the fact that only Norwich's interpretation maintains the integrity and utility of the FDA regulation that implements the section viii framework is persuasive evidence that Norwich's interpretation is correct. Conversely, if this Court credits Salix's position that Section 271(e)(4)(A) forbids district courts from crafting 271(e) orders that permit FDA approval of ANDAs amended with a section viii carve-out after infringement, FDA's regulation would be rendered void. Moreover, it would impose a temporal limitation on the use of the section viii mechanism that is wholly absent from the statute.

Salix's suggestion that the FDA regulation doesn't apply because Norwich is appealing the scope of the 271(e) order is also wrong. Salix Responsive Br. at 51-

52. The "final decision from which no appeal has been or can be taken" refers to the merits decision on infringement. Norwich has forgone its right to appeal the District Court's decision that the HE Patents are valid and infringed by the original ANDA with the HE Indication and it is therefore final. Indeed, FDA itself declined to adopt Salix's argument that the regulation doesn't apply when Salix offered it in the District of Columbia litigation. Furthermore, Salix's argument that court orders might overrule FDA regulation (Salix Responsive Br. at 5) does not alter the fact that only Norwich's interpretation of Section 271(e)(4)(A) is consistent with FDA regulation, while Salix's interpretation renders it meaningless.

D. Salix's Interpretation Is Contrary to Fundamental Principles of Patent Law.

Salix does not dispute the general principle of patent law that an injunction should be "specifically tailored" to the infringement. Norwich Br. at 24 (citing cases). Nor does it dispute that a 271(e) order that references the HE Indication – the sole basis for infringement here – is tailored to the infringement finding, whereas the order that the District Court issued is not. Indeed, Salix fails to point to any statutory or legal justification for a 271(e) order that delays the approval of an ANDA for any reason other than the basis for which the ANDA infringes a patent.

Salix also fails to rebut Norwich's argument that patent law encourages infringers to design around the infringed patent, and that the section viii provision

in the Act provides the mechanism for doing so in the Hatch-Waxman context. Norwich Br. at 25-26. Salix offers only that Norwich can refile the Amended ANDA as a new ANDA to get a different ANDA number. Salix Responsive Br. at 53. But, that puts form over substance and ignores that, as discussed above, FDA has a specific regulation that enables ANDA filers to submit a section viii statement with a carved out label in these circumstances (allowing FDA to avoid a redundant review of the identical application save for the HE Indication in the label). Moreover, Salix fails to mention the reason behind its suggestion that Norwich file a new ANDA, which is that Norwich would then be subjected to a second 30-month stay of approval, unjustifiably prolonging Salix's monopoly. Nowhere in patent law is there any basis for an injunction on marketing a product that has been redesigned to avoid infringement, nor is there any basis for it in the Hatch-Waxman Act or FDA regulation. To the contrary, "patent law encourages competitors to design or invent around existing patents." *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1355 (Fed. Cir. 1999).

E. Salix's Collection of 271(e) Orders From Other Cases Does Not Speak to the Issue Here.

The 271(e) orders that Salix points to that reference only the ANDA number do not support its incorrect statutory interpretation. Salix Responsive Br. at 41-42. The large majority of ANDA cases where infringement is found do not resemble the facts here, where there are two approved indications covered by patents listed

in the Orange Book and the generic challenger succeeds in invalidating the patents covering one of those indications. Instead, most ANDA cases involve infringement of a drug or drug product, neither of which can be carved out of an ANDA using section viii, or lack the split decision between patents covering two distinct approved indications. This is reflected in the 271(e) orders cited by Salix, none of which mirror the facts here. *Id.* In short, in the typical ANDA case, there either is no infringed method-of-use patent or else it makes no practical difference whether the 271(e) order references the infringing indication.

The order from the *Onyx v. Cipla* matter is not to the contrary. Salix Responsive Br. at 43. Although Salix relies on the parties' briefing rather than any court opinion in its discussion of this case, it is clear that the defendant was contemplating a change to the *formulation* of its product, *see id.*, and that the patent claims at issue were to compounds rather than methods of use. *See Onyx Therapeutics, Inc. v. Cipla Ltd.*, No. 20-1875, Dkt. 19 at PDF p. 2-3. Unlike the removal – or carve-out – of an indication, section viii cannot be used to amend an ANDA to change the formulation. *See* 21 U.S.C. § 355(j)(2)(A)(viii). And material formulation changes require recertification of a Paragraph IV certification. 21 C.F.R. § 314.94(a)(12). *Onyx* thus has no bearing on the issue presented here.

In fact, the only 271(e) order offered by either party that is based on a relevantly similar fact pattern is from the *Novartis v. West-Ward* case. Norwich

Br. at 22-23 (citing Appx3925-3926). There, the district court distinguished between indications in the 271(e) order so that West-Ward could use the section viii mechanism to carve out the indication covered by the later-expiring patent and go to market after expiration of the earlier patent. *Id.* Salix's argument that the 271(e) order there was agreed to by the parties misses the point. Salix Responsive Br. at 44. The district court sanctioned the agreed-upon order, which it presumably would not have done if Salix were correct that Section 271(e)(4)(A) *forbids* the reference to the infringing indication in such orders. *See E.E.O.C. v. Hiram Walker & Sons, Inc.*, 768 F.2d 884, 889 (7th Cir. 1985) (a consent judgment must be "lawful, fair, reasonable, and adequate").

F. Salix's Reliance on *Ferring* Is Misplaced and Alleged Unfairness and Prejudice Incorrect.

Salix devotes more than a third of its argument to the *Ferring* case. Salix Responsive Br. at 45-50, 52. *Ferring* does not touch on the issues presented here, however, and Salix's reliance on the case is misplaced.

As an initial matter, the district court in *Ferring* did not find that the "operative ANDA" (i.e., the amended ANDA) infringed and consequently *did not enter any 271(e) order*. Salix Responsive Br. at 45 (citing *Ferring B.V. v. Watson Labs., Inc.-Fla.*, 764 F.3d 1382, 1387, 1391 (Fed. Cir. 2014)). *Ferring* is therefore silent on the central issue before this Court, i.e., whether Section 271(e)(4)(A)

required the District Court to reference the infringing HE Indication in its 271(e) order.

Ferring also did not address any issue concerning the "*use of [a drug] claimed in a patent*." 35 U.S.C. § 271(e)(2)(A). The disputed patent in *Ferring* concerned a product claim – an oral dosage form having a specific drug release profile. 764 F.3d at 1385-86. Because the "operative ANDA," as modified, continued to seek approval of the product before the expiration of the patent, it necessarily maintained a Paragraph IV certification stating that the disputed patent was invalid or not infringed. In contrast, Norwich withdrew its Paragraph IV certification and submitted section viii statements to the HE Patents, confirming that Norwich does not seek approval for any use claimed by the HE Patents based on patent use codes authored and provided to FDA by Salix. Norwich Br. at 6.

Furthermore, unlike the defendant in *Ferring*, Norwich did not ask the District Court to "reconsider[] its judgment of infringement" in light of the ANDA amendment. Salix Responsive Br. at 46 (quoting *Ferring*, 764 F.3d at 1392). Indeed, Norwich had not yet amended the ANDA when the District Court issued its Final Judgment and 271(e) order, as Salix itself acknowledges. *Id.* at 47 (noting that the facts of this case "contrast sharply with *Ferring*"). And contrary to Salix's disingenuous suggestion (Salix Responsive Br. at 60), Norwich also did not request a finding of noninfringement for the Amended ANDA in its Rule 60(b) motion.

See, e.g., Appx3976 (reiterating that "Norwich does not ask this Court for a 'summary adjudication' of noninfringement on the merits . . . ."); Appx3968 (motion requesting only the entry of a proposed amended final judgment); Appx3999-4000 (proposed amended final judgment).[3] Thus, the "key principles" that Salix elicits from *Ferring* – that district courts have discretion whether to consider post-trial ANDA amendments but must evaluate infringement if it does so – have no relevance here. Salix Responsive Br. at 46.

Finally, because the issue of a district court's "discretion" to consider a post-trial ANDA amendment is not raised by the facts here, Salix's attempt to shoehorn its appeal to "unfairness and prejudice" into the *Ferring* framework must fail. *See id.* at 47-50, 52. There is also no basis for that appeal.

First, Norwich's interpretation of Section 271(e)(4)(A) in no way equates to an evasion or nullification of the District Court's infringement judgment. *Id.* at 48-49; *see also id.* at 35-36. On the contrary, the infringement judgment will remain in full force and continue to block Norwich from obtaining FDA approval for the HE Indication until the expiration of the HE Patents. Salix further complains that Norwich's interpretation would mean that "[a] district court could never restrict

[3] As Norwich pointed out in its principal brief (Norwich Br. at 33) and Salix does not dispute, given that FDA views the 271(e) order as blocking approval of the Amended ANDA, the District Court's order and subsequent denial of Norwich's motion is tantamount to a "summary" win for Salix that Norwich's Amended ANDA somehow infringes the HE Patents.

FDA's ability to approve an amended ANDA." *Id.* at 48. But Salix has not and cannot point to any legal basis for a 271(e) order that goes *beyond* the bounds of the underlying infringement judgment.

Second, Salix's assertion that "a generic entrant would be better off not amending until after judgment" is incorrect. *Id.* at 49. In line with the Hatch-Waxman Act's encouragement for generics to challenge weak patents, Norwich mounted a good-faith challenge to the validity of the HE and IBS-D Patents with the goal of obtaining approval for both indications. It would obviously be beneficial both for patients and for Norwich if Norwich's generic rifaximin product could be marketed for all approved indications. As it turned out, however, the District Court did not agree that the HE Patents are invalid, and the effort and expense that Norwich poured into those patents was for naught. Contrary to Salix's assertion, therefore, Norwich would have been "better off" had it carved the HE Indication *before* submitting the ANDA to FDA.

Moreover, even if generics would be "better off" by waiting to amend until after trial as Salix contends, that would not support Salix's interpretation of Section 271(e)(4)(A). On the contrary, that would only further encourage generics to challenge all Orange Book method-of-use patents perceived to be weak in an effort to obtain approval for all approved indications. And if the generic is unsuccessful with respect to one such indication as was the case here, it is

nevertheless able to obtain FDA approval and go to market for the indication it proved would *not* infringe any valid patent, consistent with Congress' intent when it designed the section viii pathway. *Supra* at 7-8. For its part, the patent owner has received the benefit of the statutory 30-month stay of approval of the ANDA while the litigation is ongoing and retains the monopoly on marketing the drug for the indication covered by its valid patent. These results are all perfectly aligned with the purpose and provisions of the Hatch-Waxman Act as well as patent law and public policy generally.

Relatedly, Salix is wrong when it contends that Norwich would "receive the same benefit as if the district court had considered the amended ANDA and found that it did not infringe." *Id.* at 49. Because infringement of the HE Patents by the Amended ANDA has not been adjudicated, Salix is free to attempt to assert any non-frivolous and non-foreclosed claims in those patents.[4] Salix is therefore wrong to suggest that there would be no "opportunity for judicial scrutiny" of the Amended ANDA. Salix Responsive Br. at 50. It is telling that Salix has not made

[4] Salix cites *GSK* for the proposition that a "skinny" label may infringe a method-of-use patent. Salix Br. at 47-48. It is worth noting that the question of inducement presented in *GSK* was not analyzed under Section 271(e)(2) but rather under Section 271(b). *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc*., 7 F.4th 1320, 1328 (Fed. Cir. 2021).

any infringement allegation, or even asserted that there could be any such infringement.

Finally, Salix's contention that it might have chosen a different litigation or trial strategy had Norwich amended its ANDA earlier does not give rise to a claim of prejudice. *Id.* at 47-48. As an initial matter, Salix chose to assert only eight of the twenty patent claims that it was permitted to pursue at trial (*see* Appx168 (stipulated order permitting presentation of 20 claims at trial); Appx3710 (listing the eight patent claims asserted at trial)), and never raised any due process complaint with respect to the trial time the District Court allotted. Further, the district court granted the parties' pretrial request (initiated by Salix) for an additional trial day providing three and one-half additional hours per side. Appx1385, Appx1907-Appx1910. Thus, Salix's suggestion that it might have raised "additional claims" or spent "additional time" on the claims it did pursue should be taken with a grain of salt. Salix Responsive Br. at 48. Moreover, Salix cannot reasonably contend that its strategy with respect to the HE Patents was somehow wasted. On the contrary, it successfully defended the validity of those patents and consequently secured a continued monopoly on marketing rifaximin for the HE Indication.

II. THE DISTRICT COURT ABUSED ITS DISCRETION IN DENYING NORWICH'S MOTION TO MODIFY THE JUDGMENT.

A. The District Court Legally Erred in Holding That Only a Money Judgment Can Be "Satisfied" Under Rule 60(b)(5).

Norwich demonstrated that the District Court committed legal error when it dismissed Norwich's request for relief under the "satisfied, released, or discharged" prong of Rule 60(b)(5) on the basis that this part of the rule applies only to money damages. Norwich Br. at 28 (citing contrary cases). Salix tacitly acknowledges the court's error when it cites cases for the proposition that this clause only "generally arises" in the context of money damages. Salix Responsive Br. at 55.

Salix complains that Norwich only cites cases from the Second, Fourth, and Ninth Circuits applying the rule in the context of injunctions. *Id.* at 56. But Salix does not contend that the absence of a case from the Third Circuit demonstrates that courts there would or should somehow apply this Federal Rule differently. Nor could it. In any event, in *Ellis v. Ethicon, Inc.*, No. 050726, 2014 WL 11462441, at *3 (D.N.J. June 2, 2014), *aff'd*, 614 F. App'x 613 (3d Cir. 2015), the New Jersey district court granted a motion under Rule 60(b)(5) seeking a determination that a Final Judgment ordering reinstatement of the plaintiff to position of quality engineer as well as money damages had been "satisfied." Thus,

the court applied the "satisfied, released, or discharged" prong of Rule 60(b)(5) not only to the money damages but also to the non-monetary portion of the injunction.

Furthermore, and as Salix surely understands, Norwich is not relying on the specific fact patterns in the cited cases "to support its argument that it 'satisfied' the judgment." Salix Responsive Br. at 56. That contention is a red herring. Rather, and as Norwich explained, Norwich's ANDA amendment satisfied the Final Judgment and Section 271(e) order because the removal of the HE Indication and corresponding Paragraph IV certifications ensures that FDA will not approve any Norwich ANDA with the infringing HE Indication until after the expiration of the HE Patents. Norwich Br. at 27-28. This constitutes the entire relief that Salix sought in its infringement claim under Section 271(e) for the HE Patents, and is exactly the relief provided in the Final Judgment and Section 271(e) order. Salix has offered no substantive argument to the contrary. *See* Salix Responsive Br. at 55-57.

B. The District Court Also Erred in Failing to Find That It Is No Longer Equitable to Apply the Order Prospectively.

Norwich also demonstrated that the District Court legally erred in holding that the "equitable" prong of Rule 60(b)(5) only applies when the change in circumstances was unanticipated or unforeseen. Norwich Br. at 30-31 (citing contrary cases). Specifically, Norwich showed that the *Rufo* case relied on by the District Court for this proposition (as well as *Rufo*'s progeny) concerned requests

to modify a *consent* judgment, while cases involving injunctions do not consider whether the change in circumstances was unexpected. *Id.*

Salix does not dispute Norwich's analysis, contending only that Norwich did not "harmonize" its argument that unforeseeability is not a consideration in the injunction context with the consent cases. Salix Responsive Br. at 59. Salix is wrong (*see* Norwich Br. at 30), but the task is not difficult in any event. When a party *consents* to a specific judgment, it is assumed to have considered potential future eventualities that might make the judgment less favorable. Thus, if that party later moves under Rule 60(b)(5) to alter the judgment because of changed circumstances, it must demonstrate that the change was not something it could have reasonably foreseen at the time it agreed to the judgment.[5] If it were otherwise, the finality and force of consent judgments would be substantially diminished. This consideration simply does not apply when the judgment or injunction was not consented to. *See Imprisoned Citizens Union v. Shapp*, 461 F. Supp. 522, 523, 529 (E.D. Pa. 1978) (affirming dissolution of injunction against use of three maximum security prison cells under Rule 60(b)(5) solely because the

[5] Salix's citation to Wright & Miller supports Norwich. Salix Br. at 57 (quoting Mary Kaye Kane, *Federal Practice and Procedure* § 2863 (3d ed. 2022)). The treatise is referring back to the "exacting" standard set out in *United States v. Swift & Co.*, 286 U.S. 106 (1932), a case involving a consent decree: "Nothing less than a clear showing of grievous wrong evoked by new and unforeseen conditions should lead us to change what was *decreed after years of litigation with the consent of all concerned*." *Id.* at 119 (emphasis added).

condition of the cells were improved so that "it is no longer equitable that our injunction against their use have prospective application").

Notably, Salix does not take issue with Norwich's demonstration that the ANDA amendment to remove the HE Indication is a "significant change . . . in factual conditions" from the time the District Court entered the Final Judgment and Section 271(e) order. Norwich Br. at 29. Instead, Salix only takes issue with Norwich's criticism of the District Court's discussion of the equities. Salix Responsive Br. at 59. Norwich has already addressed Salix's incorrect arguments in that regard. *Supra* at 16-19.

C. The District Court Further Erred in Failing to Even Consider Norwich's Motion Under Rule 60(b)(6).

While Salix does not appear to dispute that the District Court erred in failing to consider Norwich's motion under Rule 60(b)(6), it contends incorrectly that Norwich did not cite the rule in its argument on the motion. Salix Responsive Br. at 60. Salix should know better given that a section heading in Norwich's reply brief reads "Salix Overlooks Norwich's Rule 60(b)(6) Argument." Appx4225.

And Salix is wrong when it contends that the situation here is not "extraordinary." Salix Responsive Br. at 60. As far as Norwich has been able to ascertain, this is the first and only instance where FDA has declined to approve an ANDA over a Section 271(e) order based on infringement of a patent for which the

ANDA provides a section viii statement and that covers a use for which the ANDA is not seeking approval.[6]

D. Salix's Other Arguments Are Meritless.

That the relief Norwich seeks is "unprecedented" as Salix puts it is not an argument against that relief. Salix Responsive Br. at 61. The lack of precedent is because the fact pattern required for this issue to arise is rare, as Salix's collection of Section 271(e) orders demonstrates. *Supra* at 11-13.

The two district court cases cited by Salix are easily distinguishable on their facts and did not involve the same relief as Norwich seeks here. Salix Responsive Br. at 61-62. As Norwich has already pointed out (Norwich Br. at 32) and Salix admits, in *Allergan, Inc. v. Sandoz* the ANDA applicant requested that the court "make a determination that Sandoz's amended ANDA does not infringe" the relevant claim. No. 09-200, 2013 WL 6253669, at *2 (E.D. Tex. Dec. 3, 2013), *aff'd*, 587 F. App'x 657 (Fed. Cir. 2014). By contrast, neither Norwich nor Salix has sought any infringement determination for the Amended ANDA. And unlike here, Sandoz had also previously stipulated to the infringement of the same patent claim directed to the same (and only) approved indication, and the district court had entered its infringement judgment based on that stipulation. *Id*., 2013 WL

[6] Salix has not offered any other example, nor has FDA in the District of Columbia litigation.

6253669, at *1, *3. Moreover, *Allergan* was also decided *before* FDA issued its regulation permitting the amendment of an ANDA and submission of a section viii statement after a finding of infringement. 21 C.F.R. § 314.94(a)(12)(viii)(A); 81 Fed. Reg. 18,766 (Oct. 6, 2016). *Forest Lab'ys v. Sigmapharm* has even less in common with the relevant facts here because it did not involve a method-of-use patent and therefore did not feature a section viii statement or labeling carve-out. No. 14-1119, 2019 WL 3574249, at *7 (D. Del. Aug. 6, 2019).

Finally, this Court should disregard Salix's statement that the stipulation of noninfringement "should also be vacated" if Norwich prevails on this appeal. Salix Responsive Br. at 63. Salix has not appealed the stipulation (if that is even possible) and the issue (if there even is one) has not been briefed. Moreover, while Salix contends that the stipulation "no longer applies," Norwich's amendment did not "change the indications of use" but rather carved out the HE Indication wholesale. And Norwich is entitled to a judgment of noninfringement on the other patents irrespective of the stipulation because Salix elected to "not present evidence of infringement" with respect to these patents at trial despite asserting them in its Complaint. Appx3710. Salix thereby "voluntarily narrowed the case to its best patents" and is "not entitled to a second trial on the unselected patents." *Nuance Commc'ns, Inc. v. ABBYY USA Software House, Inc.*, 813 F.3d 1368,

1374, 1376 (Fed. Cir. 2016) (affirming judgment of noninfringement as to patents asserted in complaint but not at trial).

CONCLUSION

For the reasons set out above, this Court should reverse the District Court and revise the Final Judgment and Section 271(e) order.

Dated: October 23, 2023

Respectfully submitted,

/s/ Chad A. Landmon

Chad A. Landmon
Matthew Becker
Matthew Murphy
Thomas K. Hedemann
Rebecca L. Clegg
AXINN, VELTROP & HARKRIDER LLP
90 State House Square
Hartford, CT 06103
(860) 275-8100
clandmon@axinn.com
mbecker@axinn.com
mmurphy@axinn.com
thedemann@axinn.com
rclegg@axinn.com

Attorneys for Defendant-Appellant Norwich Pharmaceuticals, Inc.

FORM 19. Certificate of Compliance with Type-Volume Limitations **Form 19**
July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 22-2153, 23-1952

Short Case Caption: Salix Pharmaceuticals, Ltd. v. Norwich Pharmaceuticals Inc.

Instructions: When computing a word, line, or page count, you may exclude any items listed as exempted under Fed. R. App. P. 5(c), Fed. R. App. P. 21(d), Fed. R. App. P. 27(d)(2), Fed. R. App. P. 32(f), or Fed. Cir. R. 32(b)(2).

The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because it meets one of the following:

☑ the filing has been prepared using a proportionally-spaced typeface and includes 5,882 words.

☐ the filing has been prepared using a monospaced typeface and includes _____ lines of text.

☐ the filing contains _____ pages / _____ words / _____ lines of text, which does not exceed the maximum authorized by this court's order (ECF No. _____).

Date: 10/23/2023

Signature: /s/ Chad A. Landmon

Name: Chad A. Landmon